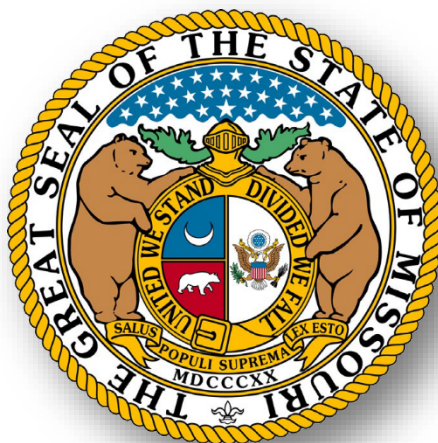




Drug Distributor Compliance Guide

May | 2023

(Revised 5/25/23)



MESSAGE FROM THE BOARD

The Missouri Board of Pharmacy is pleased to provide the *Missouri Drug Distributor Compliance Guide*. The *Compliance Guide* is designed to increase licensee compliance by providing guidance on basic provisions of Missouri's law governing drug distributors.

The Missouri Board of Pharmacy is an autonomous Board within the Division of Professional Registration, an agency of the Missouri Department of Insurance, Financial Institutions and Professional Registration. The Board consists of seven (7) members, including, one (1) public member and six (6) licensed pharmacists actively engaged in the practice of pharmacy in Missouri. Since 1909, the Missouri Board of Pharmacy has served Missouri citizens through the regulation and licensing of the pharmacy profession and drug distributors in the state of Missouri.

Additional compliance resources and materials are available on the Board's website at <http://pr.mo.gov/pharmacists>. License and regulatory updates are also provided via e-alerts and the Board's electronic newsletter. To sign up for the Board's newsletter and e-alerts, visit www.nabp.net/indexmobop.asp or e-mail MissouriBOPNewsletter@nabp.net.

This Missouri Drug Distributor Compliance Guide is provided for informational purposes only. The Compliance Guide does not constitute a rule statement of general applicability or binding law. Additionally, the Compliance Guide does not constitute a comprehensive review of all governing law or controlled substance requirements. To ensure compliance, licensees should thoroughly review Chapter 338, RSMo, 20 CSR 2220 and all other applicable state and federal laws. Statutes/rules may have changed since this document was issued. In the event of a conflict or inconsistency, duly promulgated or enacted state or federal law shall control. The term "should" represents Board/staff recommendations. The Board of Pharmacy expressly reserves the right to revise the contents as deemed appropriate or necessary. Questions regarding this document may be addressed to the Board office.

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Section 1. Missouri Licensing Requirements

- 1.1 GENERAL REQUIREMENTS.** Pursuant to [§ 338.330](#), RSMo, all “wholesale drug distributors” must be licensed or registered by the Board. A separate drug distributor license/registration is required for each distribution site. [\[20 CSR 2220-5.020\(7\)\]](#).

A “wholesale drug distributor” is defined as any person/entity engaged in delivering or distributing legend drugs or drug-related devices and who is involved in the actual, constructive, or attempted transfer of a drug in this state to any person/entity other than the ultimate consumer. [\[20 CSR 2220- 5.020\(1\)\]](#). This definition includes, but is not limited to,:

- Brokers
- Independent wholesale drug traders
- Jobbers
- Manufacturers (Missouri doesn’t issue a separate manufacturer license.)
- Own-label distributors
- Private label distributors
- Retail pharmacies conducting wholesale distributions
- Warehouses (i.e.- chain, manufacturer and wholesale warehouses)

**Missouri issues a separate third-party logistics (3PL) provider and drug outsourcer license (see Board rules in [20 CSR 2220-8](#) for additional guidance)*

A distributor license is not required if drugs are being delivered, distributed, or transferred directly to the ultimate consumer (i.e.- the patient). [\[§ 338.330\(4\)\]](#). The ultimate consumer does not include practitioner offices (physician, dentist, veterinarian, etc.), hospitals, nursing home facilities, ambulance/fire districts, other distributors, or intra-company transfers. ***Note: A Missouri pharmacy license is required to fill/dispense a patient specific prescription.***

For purposes of drug distributor licensing, a “legend drug” or “prescription drug” is defined as any drug or biological product:

- a. Subject to Section 503(b) of the Federal Food, Drug and Cosmetic Act, including finished dosage forms and active ingredients subject to such Section 503(b); or
- b. Required by any applicable federal or state law or regulation to be dispensed by prescription only or that is restricted to use or dispensed by practitioners only, or;
- c. Required under federal law to be labeled with one of the following statements prior to being dispensed or delivered:
 - i. “Caution: Federal law prohibits dispensing without prescription”;
 - ii. “Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian”; or
 - iii. “Rx Only”. [\[§ 338.330\(1\)\(a\)\]](#).

The term "drug", "prescription drug", or "legend drug" does not include:

- a. An investigational new drug, as defined by 21 CFR 312.3(b), that is being utilized for the purposes of conducting a clinical trial or investigation of such drug or product that is governed by, and being conducted under and pursuant to, 21 CFR 312, et. seq.;
- b. Any drug product being utilized for the purposes of conducting a clinical trial or investigation that is governed by, and being conducted under and pursuant to, 21 CFR 312, et. seq.; or

- c. Any drug product being utilized for the purposes of conducting a clinical trial or investigation that is governed or approved by an institutional review board subject to 21 CFR Part 56 or 45 CFR Part 46. [\[§ 338.330\(1\)\(b\)\]](#).

Drug distributors must also comply with state and federal controlled substance registration/licensure requirements. Licensees should contact the DEA or the Missouri Bureau of Narcotics and Dangerous Drugs (BNDD) which regulates controlled substances in Missouri.

Drug distributor facilities may not be located in a residence, regardless of zoning, or share an address/physical space with a business that is not related to distributing drugs or drug related device or that is not licensed and regulated by Missouri. [\[20 CSR 2220-5.030\(3\)\(O\)\]](#)

The U.S. Food and Drug Administration (FDA) has proposed national federal drug distributor and third-party logistics licensing rules that are currently pending federally. Additional licensing guidance will be issued by the Board once the federal rules are finalized.

- 1.2 EXEMPTIONS.** By law, “wholesale drug distribution” does not include, and a Missouri drug distributor license is not required for the following:

Drug Distributor License Exemptions	Additional Requirements/Guidance
1. Common carriers or individuals hired solely to transport legend drugs (i.e.- delivery services, FedEx or UPS) [§ 338.330(4)] ;	
2. Distribution of drugs from an out-of-state wholesale distributor to a Missouri licensed drug distributor in an emergency situation. [20 CSR 2220-5.050(3)]	- Exemption only applies to distributions from a non-resident wholesale distributor to a Missouri licensed wholesale distributors. The nature of the emergency should be documented in the both the shipping and receiving distributor’s records. - The amount distributed must be limited to the emergency situation but cannot exceed more than one percent (1%) of the total annual gross sales of the unlicensed distribution site. - The distribution amount is confined to the emergency. Shipments that exceed the amount needed to address the identified emergency will be considered unauthorized and unlicensed activity.
3. The sale, purchase, transfer, or trade of a drug for emergency administration to an individual patient if a delay in therapy would negatively affect a patient outcome. [20 CSR 2220-5.020(1)(B)1.]	The amount distributed is limited to 5% of the pharmacy’s total gross prescription sales or, if prescriptions are not sold, 5% of the pharmacy’s total drug purchases
4. The sale, purchase, transfer, or trade of blood and blood components intended for transfusion [20 CSR 2220-5.020(1)(B)2.]	
5. The sale, purchase, transfer, or trade of a drug by a Missouri licensed pharmacy that does not exceed five percent (5%) of the pharmacy’s total gross sales. [20 CSR 2220-5.020(1)(B)3.]	Total gross sales are calculated based on the pharmacy’s total annual prescription drug sales or, if prescriptions are not sold, five percent (5%) of the pharmacy’s total drug purchases

Drug Distributor License Exemptions	Additional Requirements/Guidance
6. The sale, purchase, transfer, or trade of drugs among hospitals or by a hospital to a healthcare entity under the same common control or ownership as the hospital. [20 CSR 2220-5.020(1)(B)4.]	Exemption applies to hospitals as defined by Chapter 197, RSMo. “Common control or ownership” means the power to direct or cause the direction of the management and policies of a person or an organization whether by ownership, stock, voting rights, contract, or otherwise. Proof of common control or ownership should be maintained in the entity’s records.
7. The sale, purchase or trade of a drug from a Class B hospital pharmacy to a hospital clinic or facility under common control, management, or ownership of the same hospital or hospital system. [§ 338.165.6]	Exemption only applies to distribution by a Class B hospital pharmacy licensed by the Board to a qualifying hospital clinic or facility. Distribution from the qualifying hospital clinic/facility to the Class B hospital pharmacy would require a Missouri drug distributor license, unless another exemption applies.
8. Storing or distributing drugs by a local, state or federal facility received from the Strategic National Stockpile or the state stockpile for the purpose of providing drugs in an emergency, as authorized by a state or federal agency. [20 CSR 2220-5.020(1)(B)5.]	Exemption applies to local, state or federal facilities only.
9. The sale, purchase, or transfer of a drug or vaccine received from or on behalf of a federal, state, or municipal entity for the purpose of treating or immunizing patients during a state or federally declared disaster or emergency. [20 CSR 2220-5.020(1)(B)6.]	
10. The sale, purchase, or transfer of a drug or vaccine subject to an emergency use authorization issued by the United States Food and Drug Administration for a public health emergency. [20 CSR 2220-5.020(1)(B)7.]	
11. The sale, purchase, transfer, or trade of a prescription drug to alleviate a temporary shortage of a prescription drug that is in limited supply or unavailable due to delays in or interruption of supply. [20 CSR 2220-5.020(1)(B)8.]	- Exemption only applies to drugs distributed/ transferred from an importer or manufacturer authorized by or registered with the FDA to import or manufacture the drug that is unavailable or in short supply. Documentation of FDA authorization or registration must be maintained in the licensee’s or recipient’s records. - Distributions/transfers must be limited to the shortage period and to the drug that is unavailable or in limited supply. The Board recommends maintaining proof of the shortage and the shortage dates. A Missouri drug distributor license would be required after the drug becomes available again, unless another exemption applies.

Drug Distributor License Exemptions	Additional Requirements/Guidance
12. The sale, purchase, transfer, or trade of a drug between a Missouri licensed pharmacy and a non-resident pharmacy that is located in and licensed by another state or United States territory. [20 CSR 2220-5.020(1)(B)9.]	- Amount distributed to or by the Missouri licensed pharmacy is limited to 5% of the Missouri pharmacy's total annual prescription sales. - The following records must be maintained for two (2) years: - Proof of the non-resident pharmacy's licensure in their home state; & - An invoice record with the name & address of the non-resident pharmacy, date of sale/distribution, and name, strength and quantity of drug received.
13. Shipments of investigational drugs.	Investigational drugs include: - An investigational new drug, as defined by 21 CFR 312.3(b), that is being utilized for the purposes of conducting a clinical trial or investigation of such drug or product that is governed by, and being conducted under and pursuant to, 21 CFR 312, et. seq.; - Any drug product being utilized for the purposes of conducting a clinical trial or investigation that is governed by, and being conducted under and pursuant to, 21 CFR 312, et. seq.; or - Any drug product being utilized for the purposes of conducting a clinical trial or investigation that is governed or approved by an institutional review board subject to 21 CFR Part 56 or 45 CFR Part 46. [§338.330.(2)(b)]
14. Intra-company shipments of drug-related devices from a non-resident wholesale distributor to an in-state wholesale distributor under common ownership	See section 1.8 and § 338.335.2 for additional requirements/restrictions.

1.3 GENERAL LICENSE REQUIREMENTS (MISSOURI FACILITIES). Applicants for drug distributor licensure must:

- Submit a completed application and pay the appropriate fee;
- Designate a manager-in-charge who is responsible for direct supervision of the distributor's operations, and;
- Pass a Board inspection.

To apply for licensure, the designated manager-in-charge must submit fingerprints and undergo a criminal background check. For non-publicly traded companies, owners with a 10% or more ownership interest must be fingerprinted and complete a criminal background check. [[20 CSR 2220-5.020\(4\)](#)]

If the facility passes inspection, the facility's drug distributor license will be approved at the close of the inspection. [[20 CSR 2220-5.020\(8\)](#)]. No receipt or distribution of legend products may occur until the facility has passed inspection and the facility's drug distributor license has been approved.

1.4 DISTRIBUTOR LICENSING FOR PHARMACIES. A Missouri licensed pharmacy may deliver or distribute legend drugs to authorized persons without a drug distributor license, provided the amount delivered/distributed does not exceed five percent (5%) of the pharmacy's total gross sales. [\[§ 338.330\(3\)\]](#). The pharmacy must be licensed as a distributor if the amount delivered/distributed exceeds five percent,. ***Note: Missouri pharmacies cannot sell or transfer drugs to other entities or healthcare practitioners by prescription. Drug sales/transfers must be documented by invoice or via CSOS/a DEA-222 form for Schedule II controlled substances. Pharmacies may not distribute compounded preparations for office stock (see [20 CSR 2220-2.200](#) exemption for compounding for use by a Missouri-licensed veterinarian). [\[§ 338.095\]](#).***

1.5 DRUG DISTRIBUTOR REGISTRANTS. In lieu of drug distributor licensure, an out-of-state drug manufacturer may apply for a Missouri drug distributor registration by filing an abbreviated drug registrant application. [\[§ 338.337\]](#). Applicants for registration must meet the following requirements:

- The applicant must be currently registered as an FDA drug manufacturer;
- The manufacturing facility must be used for both the production (manufacture) and distribution of legend drugs;
- The manufacturing facility must hold a drug distributor/manufacturer license that is current and in good standing in the state or jurisdiction where the facility is located. Inspection reports or statements of Good Manufacturing Practice (GMP) compliance/certification are insufficient; and
- The manufacturing facility must have been successfully inspected and approved by the Food and Drug Administration within the last two (2) years. A copy of the applicant's most recent Food and Drug Administration Establishment Inspection Report (EIR) must be submitted with the registration application. The application may be denied, probated or further reviewed by the Board if an FDA Form-483 has been issued. [\[20 CSR 2220-5.050\(4\)\]](#)

Registrants may conduct wholesale drug distribution in the state of Missouri, provided the registrant complies with all Missouri drug distribution standards. ***Note: Only non-resident manufacturers are eligible for a drug distributor registration; Manufacturing facilities located in Missouri cannot apply for a drug distributor registration.***

1.6 OUT-OF-STATE DISTRIBUTORS. Missouri law prohibits out-of-state wholesale drug/pharmacy distributors from shipping, mailing or delivering prescription drugs and drug-related devices into this state without a Missouri drug distributor license/registration. [\[§ 338.333\]](#). A separate distributor license must be obtained for each site/address shipping products into Missouri. [\[§ 338.335\]](#). *[See [Section 1.9](#) for intra-company device shipments.]*

To be eligible for licensure, applicants must be located in a state/foreign jurisdiction that extends reciprocal treatment to Missouri distributors and has comparable legal standards for drug distributor licensure. [\[§ 338.333\]](#). Out-of-state applicants must:

- Submit a completed application with the applicable fee;
- Designate a manager-in-charge responsible for daily supervision of the distributor's operations;
- Hold a valid license in good standing in the state or foreign jurisdiction where the applicant is located (see additional information below), and;

- Hold a valid controlled substance registration/authorization, if controlled substances will be shipped into Missouri. Alternatively, applicants may attest on their application that their home state/jurisdiction does not issue a separate controlled substance registration, if applicable. [\[20 CSR 2220-5.050\(2\)\]](#).

The designated manager-in-charge and all owners with more than a 10% interest must submit proof of fingerprinting and undergo a criminal background check. [\[20 CSR 2220-2.450\]](#).

The Board issues a wholesale drug distributor license to all entities that meet Missouri's statutory definitions of a wholesale distributor, regardless of the type of distribution activity performed. For example, both drug manufacturers and drug repackagers would be licensed in Missouri as a wholesale drug distributor. The Board recognizes other states may license drug distributor activities under different names (e.g., a manufacturer/supplier/repacker license). Different licenses from other states may be used to apply for a Missouri wholesale drug distributor license regardless of the license type, provided the applicant's home state license allows them to engage in a drug distribution activity under Missouri's definition.

The Board does not routinely inspect out-of-state facilities. However, a copy of the out-of-state facility's most recent inspection report must be submitted with the application. [\[20 CSR 2220-5.050\(2\)\(A\)6.\]](#). Inspection findings/deficiencies may result in further review by the Board.

The Board recognizes other states may not issue or require a license for distribution activities, however, Missouri law requires that non-resident applicants must be licensed in their home state to perform drug distribution activities in order to obtain a Missouri license. General business licenses cannot be accepted. Entities should contact their home state about obtaining a voluntary license, even if not required by law in their home state.

- 1.7 DRUG SALES REPRESENTATIVES.** Drug sales representatives and other agents or employees of a licensed/registered distributor may have legend drugs in their custody if the representative, agent or employee is acting in the usual course of his/her business or employment. [\[20 CSR 2220-5.030\(5\)\]](#). A drug distributor license is not required for sites used to store drugs in the custody of a drug sales representative or other agent/employee. The name and address of the drug sales representative or agent/employee must be reported to the Board along with the address of all sites where drugs are stored. Licensees must ensure that prescription drugs in the custody of a drug sales representative or other agent/employee are stored and transported in accordance with manufacturer or USP guidelines. [\[20 CSR 2220-5.030\(5\)\]](#).
- 1.8 Virtual Manufacturers.** Virtual manufacturers generally include entities that outsource their manufacturing and distribution operations to another entity without taking possession of the product. Virtual manufacturers located outside of Missouri that meet this definition do not need a Missouri drug distributor license if they do not physically handle prescription drugs. For virtual manufacturers located in Missouri, a Missouri whole drug distributor license is required if the entity is involved in the constructive transfer of prescription drugs (ordering drugs, directing shipments, brokering drug sales/transactions) [see [20 CSR 2220-5.020\(1\)\(A\)](#)]
- 1.9 Device Distributors.** Missouri law requires a drug distributor license for facilities distributing, providing, or offering legend drug-related medical devices to any person other than the ultimate

consumer/patient. [\[§ 338.330\(4\)\]](#). A “drug-related medical device” refers to devices that contain a legend drug as part of the device. [\[20 CSR 2220-5.030\(9\)\]](#). Legend items include one of the following statements on their label:

- “Rx only”
- “Caution: Federal (U.S.A.) law prohibits dispensing without a prescription.”
- “Caution: Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.”
- “Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician”.

Examples of drug-related devices may include, but are not limited to, pre-filled heparin/saline syringes, convenience kits containing a legend drug, and sterile water/saline for irrigation or inhalation.

A Missouri drug distributor license is not required for facilities distributing legend devices that do not contain a legend drug as part of the device. Additionally, a license is not required if devices are only being distributed to the ultimate consumer/patient. [\[§ 338.330\(4\)\]](#). ***Note: The ultimate consumer does not include practitioner offices (physician, dentist, veterinarian, etc.), hospitals, nursing home facilities, ambulance/fire districts, home medical equipment providers, other distributors, or intra-company transfers.***

Over-The-Counter Devices: Distribution of over-the counter devices such as blood glucose testing supplies and insulin syringes/needles does not require a distributor license. However, a Missouri pharmacy license is required if the facility chooses to dispense over-the-counter products to patients as a prescription (applicable pharmacy law would apply).

Device Distributor Exemptions: A drug distributor licensure exemption exists for out-of-state intra-company transfers of drug-related devices. Specifically, [§ 338.335.2](#) provides the following exemption:

2. A wholesale drug distributor distributing drug-related devices in Missouri is not required to obtain a license from the board for out-of-state distribution sites owned by the wholesale drug distributor if:

(1) The wholesale drug distributor has one or more distribution sites located in Missouri, and all such in-state distribution sites receiving shipments of drug-related devices are licensed by the board as a distributor;

(2) The wholesale drug distributor's out-of-state distribution sites shipping to the in-state distribution site are in compliance with their respective state's licensing laws;

(3) The wholesale drug distributor's out-of-state distribution sites that deliver drug-related devices regulated by the board into Missouri for patient use deliver such devices only to the licensed wholesale drug distributor's in-state distribution site.

1.10 MEDICAL GAS DISTRIBUTORS. Pursuant to [20 CSR 2220-5.070](#), a Missouri drug distributor license is required for any person or entity engaged in the distribution of medical gas pursuant to a medical gas order to medical gas suppliers or any other entity authorized to use, administer or distribute medical gasses. For purposes of drug distributor licensing, “medical gases” are

defined as compressed and liquid gases that a distributor or manufacturer has labeled for medical use in compliance with federal law. [\[20 CSR 2220-5.070\(2\)\]](#).

A Missouri drug distributor license is **not** required if medical gases are being dispensed solely to individual consumers (i.e.- the patient). The ultimate consumer does **not** include practitioner offices (physician, dentist, veterinarian, etc.), hospitals, nursing home facilities, ambulance/fire districts, other distributors, or intra-company transfers.

Medical gas distributors are required to comply with all Missouri drug distributor requirements, including, all security, drug storage, recordkeeping and facility requirements. However, medical gas distributors engaged in storing, transferring or transfilling medical gases other than nitrous oxide are exempt from, and do not have to comply with, the following distributor requirements:

- Thermostatically maintaining distributor facilities and taking/recording daily temperature logs;
- Maintaining temperature and humidity recording equipment;
- Ensuring drug products are raised above floor level and placed on a pallet;
- Ensuring the facility's outside premises are well-lit;
- Separating medical gases labeled for veterinary use from medical gases distributed for human use;
- Maintaining an alarm system to detect entry after hours, and
- Maintaining refrigeration/freezer units. [\[20 CSR 2220-5.070\(3\)\]](#).

Medical gas distributors that store, transfer or transfill nitrous oxide are exempt from, and do not have to comply with, the following requirements:

- Thermostatically maintaining distributor facilities and taking/recording daily temperature logs;
- Maintaining temperature and humidity recording equipment;
- Ensuring drug products are raised above floor level and placed on a pallet;
- Separating medical gases labeled for veterinary use from medical gases distributed for human use, and;
- Maintaining refrigeration/freezer units. [\[20 CSR 2220-5.070\(3\)\]](#).

In addition to Missouri's requirements, entities engaged in manufacturing/transfilling medical gases must be registered with the Food and Drug Administration (FDA) as a medical gas manufacturer and comply with all federal drug listing and current good manufacturing practice requirements. [\[20 CSR 2220-5.070\(4\)\]](#). ***Note: Medical gas cylinders and containers must bear a complete, intact, and legible drug label that includes the lot number.***

- 1.11 Pharmacy Off-Site Storage Facilities.** [20 CSR 2220-2.010\(1\)\(J\)](#) of the Board's pharmacy rules allows a pharmacy to store medication at an offsite facility that is used to distribute drugs for the pharmacy's operations. A Missouri drug distributor license is not required if the off-site storage facility is only used to store or distribute drugs for/to the applicable pharmacy. A Missouri drug distributor license **is** required if the offsite storage facility will be used to store/distribute medication for multiple pharmacies, regardless of ownership. [\[20 CSR 2220-2.010\(1\)\(J\)\]](#)

Section 2. Facility Requirements

2.1 GENERAL REQUIREMENTS. Distributors must comply with all applicable state/federal laws governing plant facilities and equipment. Additionally, facilities must comply with the following minimum requirements:

- Facilities must be suitably sized and constructed to allow proper operation, cleaning and maintenance of the distributorship [\[20 CSR 2220-5.030\(3\)\(A\)\]](#);
- The facility's drug distributor license must be posted/displayed in a public area. [\[20 CSR 2220-5.030\(3\)\(D\)\]](#). Licenses posted/displayed in private areas with restricted access are non-compliant (i.e.- a locked office);
- The outside perimeter of the facility must be well lit at all times. [\[20 CSR 2220-5.030\(3\)\(C\)12.\]](#). Motion sensitive lighting may be used, however, equipment should be routinely tested to ensure adequate functioning and movement detection;
- All aisles, walkways and shelves must be clear of debris, dirt or other filth [\[20 CSR 2220-5.030\(3\)\(C\)1.\]](#);
- Refrigeration must be available with sufficient storage space for storing all drug products that require refrigeration/freezing. [\[20 CSR 2220-5.030\(3\)\(E\)\]](#). *Note: Refrigeration is not required if the facility does not store or distribute drugs that require refrigeration/freezing.* [See also [Section 5.2- Refrigeration](#)], and;
- Appropriate sewage disposal and a hot and cold water supply must be available. [\[20 CSR 2220-5.030\(3\)\(C\)11.\]](#). Water supplies may be located in a separate part of the facility, however, the area must be accessible to staff/employees.

The Board has statutory authority to enter and inspect facilities to ensure compliance with Missouri law. [\[§338.150\]](#) Drug distributor facilities may not be located in a residence, regardless of zoning, or share an address/physical space with a business that is not related to distributing drugs or drug related device or that is not licensed and regulated by Missouri. [\[20 CSR 2220-5.030\(3\)\(O\)\]](#)

2.2 SECURITY. Adequate security policies and procedures must be established and maintained to prevent theft or diversion. [\[20 CSR 2220-5.030\(3\)\(C\)14.\]](#). At a minimum, facilities must comply with the following security requirements:

- Facilities must be equipped with an adequate security system that includes an alarm system capable of detecting entry after hours. [\[20 CSR 2220-5.030\(3\)\(C\)13.\]](#). Security cameras alone are insufficient. While cameras may record unauthorized entry, they generally do not protect against theft and diversion as required by law. The Board recommends security systems that are able to promptly detect unauthorized entry and provide timely alerts.
- The facility's security systems must protect against theft or diversion facilitated by tampering with computers or electronic records. [\[20 CSR 2220-5.030\(3\)\(C\)14.\]](#).
- Facilities must be equipped with sufficient locking mechanisms to prevent theft or diversion. [\[20 CSR 2220-5.030\(3\)\(C\)14.\]](#). Manual, biometric or electronic equipment may be used.

Additionally, drugs held for distribution must be stored in a secure area that can only be accessed

by authorized personnel. [\[20 CSR 2220-5.030\(3\)\(H\)\]](#). Distributors must maintain a list of all current staff with keys, passes or codes that will allow them to independently access any part of a facility where controlled substances are stored or where drugs are stored for later distribution. [\[20 CSR 2220-5.030\(3\)\(H\)\]](#). Additionally, licensees must maintain a record of all former employees who have had access to drug storage or processing areas. [\[20 CSR 2220-5.030\(3\)\(H\)\]](#). Records must be maintained for three (3) years and must be available or retrievable during inspection. [\[20 CSR 2220-5.030\(3\)\(H\)\]](#).

- 2.3 TEMPERATURE/HUMIDITY CONTROLS.** Distributor facilities must be thermostatically maintained and equipped with appropriate temperature and humidity recording devices/equipment. [\[20 CSR 2220-5.030\(3\)\(B\)\]](#). A drug storage area is non-compliant if the area is not heated or air conditioned.

Temperature and humidity readings should be taken and recorded daily. Manual, electronic or electromechanical equipment may be used for readings, however, equipment should be regularly tested to ensure proper functioning. [\[20 CSR 2220-5.030\(3\)\(B\)\]](#). Proof of temperature/humidity documentation will be requested during an inspection. Facility staff monitoring temperature/humidity readings should be trained on what appropriate temperature(s) and humidity levels are and what to do if a reading is out of range.

Note: The Board continues to cite violations because of broken or malfunctioning temperature/humidity equipment. Devices should be regularly checked to ensure proper functioning.

Section 3. Policies & Procedures

- 3.1** Distributors must establish and maintain written policies and procedures for receiving, storing, securing, inventorying, and distributing prescription drugs. [\[20 CSR 2220-5.030\(3\)\(M\)\]](#). At a minimum, the facility's policies and procedures must include policies/procedures for:
- 1) Identifying, recording and reporting losses or thefts;
 - 2) Product receipt, storage and distribution;
 - 3) Product security;
 - 4) Stock rotation;
 - 5) Correcting inventory errors and inaccuracies;
 - 6) Handling prescription drug recalls/withdrawals;
 - 7) Preparing for, protecting against and handling the security or operation of a facility in the event of a strike, fire, flood or other natural disaster, or any other local, state or national emergency;
 - 8) Reporting counterfeit or suspected counterfeit drugs, devices or other activities to the Board;
 - 9) Reporting any prescription drug shortage to the Board and any other appropriate federal/state agency where it is known or suspected that diversion or theft is occurring;
 - 10) Investigating discrepancies involving counterfeit, suspected counterfeit or contraband drugs in the facility's inventory and reporting such discrepancies to the appropriate federal or state agencies within seven (7) business days;
 - 11) Reporting criminal or suspected criminal activities involving drug inventory to the Board within seven (7) business days;

- 12) Segregating outdated prescription drugs;
- 13) Security procedures for delivering drugs from the facility to the destination site, and;
- 14) Destroying outdated prescription drugs or returning outdated prescription drugs to the manufacturer. Written documentation of the disposition of outdated drugs is required. [\[20 CSR 2220-5.030\(3\)\(M\)\]](#)

Failure to adhere to required policies/procedures could result in disciplinary action.

Note: Failure to maintain a complete policy and procedure manual is a common violation. Licensees should regularly review [20 CSR 2220-5.030](#) to ensure compliance. Distributor staff should know the location of the policy and procedure manual so it may be located during an inspection. Failure to produce the policy and procedure manual may result in an inspection violation.

Section 4. Staff/Personnel

- 4.1 Manager-In-Charge.** Distributor operations must be conducted under the direct supervision of a manager-in-charge (MIC) that has been properly designated with the Board. [\[20 CSR 2220-5.030\(2\)\(E\)\]](#). To be designated, the MIC must have two (2) years of experience/education in:
- A wholesale/pharmacy distributor facility;
 - Drug distributor law, standards of operation or compliance, or;
 - Any educational endeavor beyond graduation from an accredited high school or its equivalent. [\[20 CSR 2220-5.030\(2\)\(B\)\]](#).

Experience and education may be combined to meet the two (2) year requirement. [\[20 CSR 2220-5.030\(2\)\(B\)\]](#).

The designated MIC is responsible for supervising distributor activities and must be actively involved in, and aware of, the facility's daily operations. [\[20 CSR 2220-5.030\(2\)\(E\)\]](#). The MIC must be **physically present** on-site during the facility's normal business hours except when absent for illness, scheduled vacations or other authorized absences. Distribution activities may be conducted during an authorized absence, however, the authorized absence should be documented in the distributor's records. [\[20 CSR 2220-5.030\(2\)\(B\)\]](#).

An individual may serve as MIC for more than one facility. However, the MIC must be regularly engaged in/involved with drug distributor operations at each facility, and must be physically present during normal business hours for each facility, as required by [20 CSR 2220-5.030\(2\)\(B\)](#).

Note: The Board recognizes that a MIC may be briefly and momentarily absent from a facility during business hours for legitimate reasons. The Board has determined distributorship operations may continue during these brief absences, provided the MIC must be otherwise actively involved in, and aware of, the facility's operations in the interim. The MIC should also ensure adequate policies and procedures are in place to ensure compliance with applicable state/federal law.

Licensees must immediately notify the Board if the designated MIC changes, resigns, or is

terminated. [\[20 CSR 2220-5.030\(2\)\(E\)\]](#). The distributorship may not continue operations until a new MIC has been properly designated with the Board by submitting a completed [Manager-In-Charge Change application](#). Newly designated MICs must satisfy all education/experience requirements and undergo a criminal background check.

The newly designated MIC may begin serving once the completed [Manager-In-Charge Change application](#) has been mailed or submitted to the Board. To be complete, the application must include the applicable fee and proof of fingerprinting (i.e.- a receipt). A copy of the application should be retained in the distributor's files.

4.2 MANAGERS/SUPERVISORS. In addition to the MIC, any person considered to be a manager or supervisor of drug distributor activities must have at least one (1) year of experience/education in:

- A wholesale/pharmacy distributor facility;
- Drug distributor law, standards of operation or compliance, or;
- Any educational endeavor beyond graduation from an accredited high school or its equivalent. [\[20 CSR 2220-5.030\(2\)\(C\)\]](#).

Experience and education may be combined to satisfy the one (1) year requirement. [\[20 CSR 2220-5.030\(2\)\(C\)\]](#). A list of all officers, directors, managers and other persons in charge of wholesale drug distribution, storage and handling must be maintained at the facility, along with a description of each individual's job duties and their qualifications. [\[20 CSR 2220-5.030\(2\)\(C\)\]](#).

The 1-year experience/education requirement applies to any person "considered" to be a manager or supervisor regardless of job title. [\[20 CSR 2220-5.030\(2\)\(C\)\]](#). The Board may consider a variety of factors when determining if an employee is considered a manager or supervisor, including, the employee's actual job duties and ability to direct, manage or supervise facility operations/staff.

4.3 STAFF/PERSONNEL TRAINING. All staff performing drug distribution activities must have sufficient education, training or experience to perform the duties assigned. [\[20 CSR 2220-5.030\(2\)\(D\)\]](#). At a minimum, staff should be sufficiently trained to ensure awareness of drug safety requirements as well as distribution standards, policies and procedures. The Board recommends ongoing training/education of all staff to ensure continued competency/compliance.

Section 5. Drug Handling/Storage

5.1 RECEIPT OF LEGEND DRUGS. Pursuant to [20 CSR 2220-5.020\(1\)](#), a drug distributor can only receive legend drugs or drug-related devices from Missouri licensed drug distributors or Missouri licensed pharmacies. Licensees are responsible for ensuring proper licensure prior to receiving a shipment. License status may be verified on the [Board's website](#). (See [Section 1.2](#) for authorized licensure exemptions.)

Once received, the outside shipping container of any legend drug must be visually examined to verify identity and to prevent acceptance of any contaminated, misbranded, adulterated, or unfit drug product. [\[20 CSR 2220-5.030\(3\)\(C\)5.\]](#). The examination must be adequate to reveal

container damage or any other damage that may suggest possible contamination. [\[20 CSR 2220-5.030\(3\)\(C\)5.\]](#)

Any prescription drug whose immediate or sealed outer/secondary container has been opened or used must be identified and physically separated from other prescription drugs until the drug product is either destroyed or returned to the supplier. [\[20 CSR 2220-5.030\(3\)\(C\)5.\]](#)

DSCSA Requirements: The federal Drug Supply Chain and Security Act (DSCSA) restricts access to the U.S. drug distribution system by requiring that prescription drug products may only be transferred between authorized trading partners. Under the DSCSA, authorized trading partners include a manufacturer, repackager, wholesale distributor, third-party logistics provider, or dispenser, as defined by federal law. [See sections 582(b)(3), (c)(3), (d)(3), and (e)(3) of the Food, Drug * Cosmetic Act (21 U.S.C. 360eee-1)]

The FDA has issued draft guidance on identifying authorized trading partners available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/identifying-trading-partners-under-drug-supply-chain-security-act> Licensees should review federal law with legal counsel to ensure prescription drugs are only transferred to/between authorized entities. Failure to comply with federal law constitutes grounds for discipline under § 338.055 of Missouri law.

- 5.2 REFRIGERATION.** Drugs must be maintained within the manufacturer's temperature recommendations and/or as recommended by USP at all times. [\[20 CSR 2220-5.030\(3\)\(B\)\]](#). Refrigeration units must be equipped with appropriate temperature reading devices or equipment. [\[20 CSR 2220-5.030\(3\)\(B\)\]](#). Adequate refrigeration storage space must be available to store all drug products requiring refrigeration/freezing. [\[20 CSR 2220-5.030\(3\)\(E\)\]](#). Refrigeration units are not required if the facility does not store or distribute drugs that require refrigeration/freezing.

Temperature readings for refrigeration/freezer units should be taken and recorded daily. [\[20 CSR 2220-5.030\(3\)\(B\)\]](#). Mobile, temporary or portable units may be used as long as drugs are stored within recommended temperature limits and temperature readings are appropriately documented. Proof of compliance will be requested during an inspection. Facility staff should be trained on what appropriate temperature(s) are and what to do if a reading is out of range.

The Board continues to cite violations because of broken or malfunctioning temperature/humidity equipment. Devices should be regularly checked to ensure proper functioning.

- 5.3 LABELING.** Prescription drugs held for wholesale distribution must be labeled with the manufacturer's name, expiration date, if applicable, batch or lot number and national drug code. [\[20 CSR 2220-5.030\(3\)\(F\)\]](#). Additionally, distributors must comply with all manufacturer, FDA and USP labeling requirements. [\[20 CSR 2220-5.030\(3\)\(F\)\]](#). *Note: Medical gas cylinders and containers must bear a complete, intact, and legible drug label that includes the lot number.*

5.4 SANITATION. Distributors must establish adequate policies/procedures to ensure drugs are stored in a clean and sanitary manner. [\[20 CSR 2220-5.030\(3\)\(C\)\]](#). Distribution of any adulterated or misbranded drug violates state and federal law and may result in disciplinary action.

At a minimum, distributors must comply with the following sanitation requirements:

- Drug storage areas must be maintained in a clean and sanitary manner at all times with appropriate housekeeping, lighting, sanitation, ventilation and humidity [\[20 CSR 2220-5.030\(3\)\(C\)\]](#);
- All aisles, walkways and shelves must be clear of debris, dirt or other filth [\[20 CSR 2220-5.030\(3\)\(C\)1.\]](#);
- Procedures must be in place to prevent, control and alleviate infestation by insects, rodents, birds or other vermin. [\[20 CSR 2220-5.030\(3\)\(C\)10.\]](#). If an infestation is suspected, distributors should immediately take steps to protect the drug supply and prevent contamination (i.e.- moving/segregating drug inventory);
- All legend drug products must be raised above floor level and placed on a pallet or similar device [\[20 CSR 2220-5.030\(3\)\(C\)4.\]](#);
- Accumulated waste/garbage must be separated and cannot be stored in the same area as drug products [\[20 CSR 2220-5.030\(3\)\(C\)7.\]](#);
- Appropriate sewage disposal must be available [\[20 CSR 2220-5.030\(3\)\(C\)11.\]](#), and;
- Animals are not allowed in drug storage areas, except for service animals as defined by the Americans with Disabilities Act (ADA). [\[20 CSR 2220-5.030\(3\)\(C\)10.\]](#)

The Board recognizes that dust cannot be entirely prevented. However, adequate ventilation and/or cleaning procedures must be used to keep dust collection at a low level. [\[20 CSR 2220-5.030\(3\)\(C\)1.\]](#). Excessive dust is unsanitary and may result in an inspection violation.

Distributors are encouraged to establish a regular scheduled time for physically checking shelves and other drug storage areas. Regular monitoring will prevent compliance issues and ensure proper maintenance.

5.5 DRUG SHIPMENTS. Distributors must establish and maintain standards of practice to ensure drugs of appropriate quality are distributed. [\[20 CSR 2220-5.030\(3\)\(M\)\]](#). Prior to shipment/distribution, all outgoing shipments of prescription drugs must be carefully inspected to verify identity and to ensure that no drug is dispensed that has been damaged in storage or held under improper conditions. [\[20 CSR 2220-5.030\(3\)\(C\)6.\]](#)

The oldest approved stock of a prescription drug must be distributed first. [\[20 CSR 2220-5.030\(3\)\(M\)1.\]](#). Distributors may temporarily deviate from this requirement if deemed appropriate. [\[20 CSR 2220-5.030\(3\)\(M\)1.\]](#). Licensees may be asked to substantiate cause for distributing newer stock during an inspection.

Distributors that conduct repackaging must also comply with all applicable with state/federal law governing:

- 1) Packaging;
- 2) Record keeping;
- 3) Expiration dating;
- 4) Production and control procedures;

- 5) Containers;
- 6) Testing, and;
- 7) Federal registration. [\[20 CSR 2220-5.030\(4\)\].](#)

5.6 INVENTORY SEGREGATION. Drugs products stored in the facility or held for distribution must be physically separated and stored away from:

- Any article, supply or drug that is outdated, distressed, misbranded or adulterated [\[20 CSR 2220-5.030\(3\)\(C\)7.\]](#);
- Any quarantined or non-usable substance [\[20 CSR 2220-5.030\(3\)\(C\)7.\]](#);
- Drugs labeled for veterinary use (human drugs must be stored separately), and; [\[20 CSR 2220-5.030\(3\)\(C\)9.\]](#)
- Any flammable article (including flammable non-drug products). [\[20 CSR 2220-5.030\(3\)\(C\)8.\]](#)

DSCSA Requirements: The federal Drug Supply Chain Security Act (DSCSA) also requires certain wholesale drug distributors, “upon determining that a product in their possession or control is a suspect product, to quarantine the product while they promptly conduct an investigation to determine whether the product is an illegitimate product.” See FDA “*Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification Guidance for Industry*” for additional information at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/drug-supply-chain-security-act-implementation-identification-suspect-product-and-notification>

Suspect product is defined in section 581(21) of the Food, Drug & Cosmetic Act (FDCA) as a product for which there is reason to believe it:

- Is counterfeit, diverted, or stolen;
- Is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
- Is the subject of a fraudulent transaction; or
- Appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans. [FDCA Section 581(21)]

Licenses should review the DSCSA to ensure compliance with suspect product quarantine requirements. [See also [section 5.10](#) for illegitimate products/FDA notification requirements]

5.7 RETURNS. Prescription drugs may only be returned to the distributorship as allowed by state/federal law. If the conditions under which a prescription drug has been returned casts doubt on the drug’s safety, identity, strength, quality, or purity, the drug must be destroyed or returned to the supplier, unless examination, testing or other investigation proves the drug meets appropriate standards of safety, identity, strength, quality, and purity. [\[20 CSR 2220-5.030\(3\)\(G\)\]](#). At a minimum, distributors must consider:

- The conditions under which the drug was held, stored, or shipped before or during its return;
- The condition of the drug as a result of storage or shipping, and;
- The condition of the drug’s container, carton or labeling. [\[20 CSR 2220-5.030\(3\)\(G\)\]](#).

Note: *Drugs not properly labeled as required by the manufacturer or the FDA are misbranded and may not be redistributed (i.e.- labels missing, removed or substantially altered/torn).*

The Board has reviewed instances where items were returned to a distributor with patient information on the container (e.g., a prescription label) and redistributed with the patient information still visible. This violates both HIPAA and Missouri law. Policies/procedures should be in place for checking returned items for confidential/protected health information prior to redistribution.

- 5.8 DRUG DISPOSAL/DISPOSITION.** Prescription drugs must be destroyed/disposed of in compliance with applicable state/federal law. Written documentation of the disposition of outdated drugs must be maintained for three (3) years after disposition. [\[20 CSR 2220-5.030\(3\)\(I\)\]](#).
- 5.9 SALVAGING/REPROCESSING.** Distributors must comply with all applicable federal, state or local laws or regulations related to prescription drug product salvaging or reprocessing, including, Parts 207, 210 and 211 of the Federal Food, Drug and Cosmetic Act. [\[20 CSR 2220-5.030\(7\)\]](#).
- 5.10 COUNTERFEIT/CONTRABAND DRUGS.** Distributors must investigate any discrepancy involving real or suspected counterfeit or contraband drugs in the distributor's inventory. [\[20 CSR 2220-5.030\(3\)\(M\)6.\]](#). Discrepancies must be reported within seven (7) business days to the Board and any applicable federal/state agency. [\[20 CSR 2220-5.030\(3\)\(M\)6.\]](#).

Distributors must also report any drug received or distributed that is found to be counterfeit in whole or in part. [\[20 CSR 2220-5.030\(3\)\(C\)7.\]](#). Reports must be filed with the Board within seven (7) days after gaining knowledge of the transaction. [\[20 CSR 2220-5.030\(3\)\(C\)7.\]](#). Reporting is not required if a recall is initiated by the FDA or a Missouri licensed vendor. [\[20 CSR 2220-5.030\(3\)\(C\)7.\]](#). *Note: Reporting is required for drugs received directly or indirectly (i.e.- through a secondary broker (paper) transaction).*

Illegitimate Products: In addition to state law, the federal Drug Supply Chain Security Act (DSCSA) requires certain wholesale drug distributors to notify the FDA and all appropriate immediate training partners within 24-hours after determining a product is illegitimate under federal law. According to FDA guidance, an "illegitimate product" means a product for which credible evidence shows that the product:

- Is counterfeit, diverted, or stolen;
- Is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;
- Is the subject of a fraudulent transaction; or
- Appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.

(See [FDA Guidance](#) for definitions of counterfeit, diverted, stolen, fraudulent transaction, and unfit for distribution)

The FDA has advised that notification of illegitimate products should be submitted to FDA by completing and e-mailing FDA Form 3911 to: drugnotifications@fda.hhs.gov with "Illegitimate Product Notification Submission" in the subject line.

- See the FDA's website at: <https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/notify-fda-illegitimate-products> for current guidelines/requirements for reporting

- illegitimate products.
- See also FDA’s March 2023 final guidance: “[Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act Guidance for Industry](#)”

See [Section 5.6](#) for additional federal requirements for suspect products.

Section 6. Records

- 6.1 GENERAL REQUIREMENTS.** Distributors must accurately maintain all records required by state and federal law, including, all records required by the Drug Enforcement Agency (DEA), FDA, and the Missouri Bureau of Narcotics and Dangerous Drugs (BNDD). The following chart summarizes selected Missouri recordkeeping requirements and is not a comprehensive listing. Licensees should thoroughly review Chapter 338, RSMo, and 20 CSR 2220-5 to ensure compliance with Missouri requirements. **Federal law may require longer record retention requirements.*

Record	Retention Period	Cite
Disposition of outdated drugs	Three (3) years after disposition	20 CSR 2220-5.030(3)(M)8.
Transaction records	Three (3) years after distribution/disposition	20 CSR 2220-5.030(3)(J)
Records of current/former employees with access to drug storage or processing areas	Three (3) years	20 CSR 2220-5.030(3)(I)
Authorized personnel listings	Three (3) years	20 CSR 2220-5.030(3)(H)
Temperature/humidity records	Three (3) years	20 CSR 2220-5.030(3)(B)
MIC and other supervisors job descriptions	Three (3) years	20 CSR 2220-5.030(6)
Controlled substance records (annual inventories, loss reports, C-II order forms, CSOS records, power of attorney forms)	Two (2) years	BNDD/DEA regulations

- 6.2 TRANSACTION RECORDS.** Licensees must maintain inventories and records of all transactions regarding the receipt, distribution or other disposition of prescription drugs. [\[20 CSR 2220-5.030\(3\)\(I\)\]](#). The facility’s transaction records must document:
- 1) The date(s) drugs were received, disposed of or distributed;
 - 2) The identity and quantity of drugs received, distributed, or disposed of;
 - 3) The source of the drugs, including, the name and principal address of the seller or transferor, and;
 - 4) If drugs are received, the address of the location shipping the drug product. [\[20 CSR 2220-5.030\(3\)\(I\)\]](#).

Note: *Records must be maintained for all drugs, including, outdated, damaged, deteriorated, misbranded or adulterated drugs.*

*The federal DSCSA includes electronic product tracing and transaction requirements for wholesale distribution, including significant requirements that are currently scheduled to take effect in November 2023. ** Licensees should review federal requirements with legal counsel to ensure facility compliance. Licensees must comply with all applicable federal requirements in addition to Missouri law. Additional FDA information is available online at: <https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-product-tracing-requirements-frequently-asked-questions> .*

***Federal date may be subject to change.*

6.3 PRODUCTION/INSPECTION OF RECORDS. Required records may be manually or electronically maintained.

- *Manual Records:* Records manually stored at the facility must be made available for inspection and photocopying during inspection. Manual records may be stored offsite provided records must be produced for inspection within two (2) working days of a request from the Board or its representative. [\[20 CSR 2220-5.030\(3\)\(K\)\]](#).
- *Electronic Records:* Licensees/registrants must be able to immediately retrieve electronically stored records during an inspection. [\[20 CSR 2220-5.030\(3\)\(K\)\]](#). Alternatively, distributors may provide a computer terminal that will allow the inspector to immediately access the system. To allow review, the inspector may ask for code information. *Note: Licensees should review DEA requirements to determine which controlled substance records may legally be maintained offsite.*

Section 7. License/Registration Changes

7.1 CHANGE OF NAME. Distributors may only conduct business under the name licensed/registered with the Board. [\[§ 338.333\]](#). A drug distributor [Name Change application](#) must be submitted if the entity conducts distribution operations under any name not reflected on the license/registration.

7.2 CHANGE OF LOCATION. A [Location Change application](#) must be filed with the Board if:

- The facility's address changes, or;
- The facility moves to another location within the existing structure that has not been inspected by the Board. *Note: This includes a change of location to another floor or other area at the same address that has not been inspected by the Board.* [\[20 CSR 2220-5.020\(6\)\]](#).

Distributor operations may not begin at a new location or address until the [Location Change application](#) has been approved and a new license has been issued. For in-state facilities, the new location must pass a Board inspection. [\[20 CSR 2220-5.020\(6\)\]](#). For out-of-state (non-Missouri) distributors, a copy of the updated license from the applicant's home state or jurisdiction must be attached to the application along with an updated copy of the applicant's state/federal controlled substance registrations, if applicable. [\[20 CSR 2220-5.050\(2\)\(A\)\]](#).

Once approved by the Board, a license will be used for the new location under the same license number. *Note: A Location Change application is not required if the facility's postal address changes but not the location. In such case, an amended license will be issued reflecting the new address without charge if requested.*

- 7.3 CHANGE OF OWNERSHIP.** A distributor license/registration is only valid for the entity/owners reflected in the facility's original application. [\[20 CSR 2220-5.020\(5\)\]](#). If a change of ownership occurs, the original distributor license will become void on the effective date of the change and cannot be transferred. The new owners must file a Missouri Change of Ownership application with the Board and obtain a new Missouri distributor license/registration prior to assuming operations. [\[20 CSR 2220-5.020\(5\)\]](#). **The new owners may not receive or distribute legend products until a temporary or permanent license has been issued for the facility under the new ownership.**

Rule [20 CSR 2220-5.020\(5\)](#) contains detailed guidelines for determining when a change of ownership has occurred. Licensees should thoroughly review the rule's requirements to ensure compliance. *Note: A change-of-ownership application will likely be required if an entity changes corporate structure (i.e.- from an LLC to an LLP/corporation/sole proprietorship).*

After the change of ownership occurs, a completed self-inspection form must be submitted to the Board office to complete the change-of-ownership application process (both resident and non-resident facilities). Missouri located facilities do not have to be re-inspected. To avoid business interruptions, a temporary pharmacy permit will be issued to the new owners after the change of ownership occurs to allow time for completing the self-inspection or issuance of the new state license for non-resident applicants (applications must be otherwise complete). [\[20 CSR 2220-5.020\(8\)\]](#) The new ownership may begin operating once the temporary license number has been issued. A permanent license will be issued with the same license number after the self-inspection form is received and all other application requirements have been met.

Temporary licenses automatically expire in twelve (12) months from the date issued and cannot be renewed. [\[20 CSR 2220-5.020\(8\)\(A\)\]](#). The temporary license will become null and void if the application is denied by the Board. *Note: Receipt of a temporary license does not guarantee permanent licensure. The Board reserves the right to deny, probate or otherwise restrict a license, as authorized by Missouri law.*

For non-publicly traded companies, all new owners with a 10% interest or more must be fingerprinted and complete a criminal history background check. [\[20 CSR 2220-2.450\]](#) The designated Manager-In-Charge (MIC) must also complete a criminal history background check, if the MIC is new or will be changing.

- 7.4 TERMINATION OF BUSINESS.** Prior to terminating drug distribution activities, licensees should ensure proper arrangements have been made for all legend drugs and records. Additionally, an [official Out-of-Business Notification Form](#) must be filed with the Board within fifteen (15) days after termination and the facility's distributor license must be returned to the Board office. [\[20 CSR 2220-5.025\]](#).

Any remaining drug inventory may be transferred/disposed of as authorized by state and federal

law. [\[20 CSR 2220-5.025\(2\)\(A\)\]](#). A complete inventory of all controlled substances being transferred or disposed of must be taken on the date of termination, as required by state/federal law. [\[20 CSR 2220-5.025\(2\)\(A\)\]](#). The inventory will serve as the final inventory of the distributor terminating business and the initial inventory of the entity receiving the transfer(s). No misbranded, outdated or adulterated drug may be transferred, except for purposes of disposal.

Distributors must identify a location where distribution records will be maintained after the facility terminates business on the facility's [Out-Of-Business Notification form](#). [\[20 CSR 2220-5.025\(1\)\(C\)\]](#). Distributor records must be retrievable within seven (7) working days of a request from the Board or an official designee. [\[20 CSR 2220-5.025\(C\)1.\]](#). ***Note: Entities changing location or ownership must file an official Location Change/Change of Ownership application with the Board.***

Section 8. Drug Quality and Security Act / Drug Supply Chain Security Act

8.1 Federal Law. The federal Drug Quality and Security Act (DQSA) was enacted on November 27, 2013, which established new requirements to enhance the quality and security of the U.S. drug supply chain. Title II of the DQSA includes the Drug Supply Chain Security Act (DSCSA), which contains requirements “to achieve interoperable, electronic trading of products at the package level to identify and trace certain prescription drugs as they are distributed in the United States.” As recognized by the FDA, the DSCSA and the DQSA will “help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful,” and “will also improve detection and removal of potentially dangerous drugs from the drug supply chain to protect U.S. consumers.”

Missouri drug distributors must comply with all applicable DSCSA and DQSA requirements. FDA compliance resources on the DSCA and DQSA are available online at: <https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa>. The Board cannot provide guidance on DSCSA/DQSA requirements.

Section 9. Mandatory Reporting

9.1 All wholesale drug distributors must report the following to the Board:

- Any final adverse action taken by another licensing state, jurisdiction or governmental agency against any license to practice or operate as a pharmacy, drug distributor, drug manufacturer or drug outsourcing facility;
- Any surrender of a license or authorization to practice as a pharmacy, drug distributor, drug manufacturer or drug outsourcing facility
- Any exclusion to participate in any state or federal funded health care program for fraud or abuse or for submitting any false/fraudulent claim for payment or reimbursement (e.g., Medicare, Medicaid or MoHealthNet).

Notification must be submitted to the Board within fifteen (15) days of the action, surrender or exclusion. Notifications can be e-mailed to the Board office at: drugdistributor@pr.mo.gov or mailed to the Board office (*e-mail is preferred*).

Section 10. Common Inspection Violations

The list below contains common deficiencies found during routine drug distributor inspections.

FACILITIES

1. Unsanitary conditions (dust, dirt, pets, cobwebs, and trash/debris)
2. Facility alarm not functioning
3. No separate area for distressed/outdated/quarantined products.
4. Veterinary products not stored separately from human products.
5. Drugs on the floor, even if boxed (drugs must be raised above the floor or placed on a pallet).
6. Missing/incomplete daily temperature recordings (rooms, refrigerator, and freezer), and/or humidity recordings for all drug storage areas.
7. Unable to produce evidence of active pest control plan.
8. Medical gas cylinders with unreadable drug label.

RECORDS

1. Missing/outdated list of personnel authorized to be in the facility.
2. Non-existent or incomplete policies and procedures. *See [Section 3](#) for Policy & Procedure requirements.*
3. Unable to locate policies and procedures.
4. No written job description of Manager-in-Charge or other distribution/control supervisors.

MISC.

1. Receiving product from unlicensed vendors.
2. Distributing to customers/entities not appropriately licensed to receive legend drugs.
3. Manager-In-Charge not present on daily basis.

BOARD OF PHARMACY



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